



Frequently Asked Questions about Raloxifene

What is raloxifene?

Raloxifene (Evista) is a medicine currently used to help prevent and treat *osteoporosis*. It is a *selective estrogen-receptor modulator (SERM)*. SERMs have also been called “designer estrogens.”

What are SERMs and how do they work?

SERMs are drugs that act on some parts of the body (such as bones) much like *estrogen* does. But they do not have estrogen-like effects on other parts of the body. In fact, SERMs can block the effects of estrogen on certain body tissues.

A SERM works by “binding” or attaching to *estrogen receptors* in the body. Not all parts of the body have estrogen receptors, and not all estrogen receptors are alike. Estrogen receptors in bone tissue are not the same as estrogen receptors in breast tissue, for example. These differences allow SERMs to have one effect in one kind of tissue and a different effect in another kind of tissue.

Tamoxifen, a drug used in breast cancer prevention and treatment, was the first SERM. Raloxifene, a very recent SERM on the market, is similar in some ways to tamoxifen. Other SERMs are being developed. Ideally, a SERM would have all the benefits of estrogen and none of the risks. So far no SERM is yet available in the U.S. that meets that standard.

How are estrogen and raloxifene different?

Taking estrogen after *menopause* has both benefits and risks. Estrogen helps with symptoms of menopause like hot flashes and vaginal dryness, and can improve cholesterol levels. Estrogen can also help prevent bone loss and osteoporosis-related fractures. Common side effects of estrogen include bleeding, breast tenderness and bloating. More serious risks of taking estrogen include uterine cancer, blood clots, breast cancer, heart disease, and stroke. Women with a uterus should take a *progestin* along with estrogen to help reduce their risk of uterine cancer.

Raloxifene has the following benefits:

- It helps prevent bone loss and increases bone density by a modest amount, helping to prevent spinal fractures.
- It does not increase the risk of uterine cancer like estrogen does.
- It does not appear to increase the risk of breast cancer like estrogen does.
- It lowers cholesterol levels slightly (estrogen has somewhat better effects).

Raloxifene does not help with symptoms of menopause like estrogen does. The most common side effects of raloxifene are hot flashes and leg cramps. And, raloxifene slightly increases the risk of blood clots.

SERMs such as raloxifene may be a better choice than estrogen for some women. A recent study has found that *hormone replacement therapy* or *HRT* (taking estrogen and a particular synthetic progesterone together) can increase a woman's risk for breast cancer, heart disease, stroke, and blood clots. In addition, another recent study has found that taking *estrogen replacement therapy* or *ERT* (taking estrogen only) can increase a woman's chances of developing ovarian cancer, especially if taken for 10 years or more.

SERMs are being studied to see if they may be better alternatives to traditional estrogen therapy after menopause.

Is it true that raloxifene can help prevent breast cancer?

Studies of raloxifene's effects on osteoporosis in postmenopausal women have found a lower risk of breast cancer in women using the drug. Further research is needed to determine if raloxifene can help prevent breast cancer in women at high risk for the disease. The National Cancer Institute (NCI) is sponsoring a study to directly compare the effects of tamoxifen and raloxifene in postmenopausal women. The trial, named STAR (Study of Tamoxifen and Raloxifene), began recruiting participants in 1999. It will follow 22,000 women for a period of 5 to 10 years. The study is being conducted at more than 500 centers across the United States, Puerto Rico, and Canada. For more information about the STAR trial, contact NCI's Cancer Information Service (see links below).

For more information...

To learn more about raloxifene, contact the National Women's Health Information Center at 1-800-994-9662 or the following organizations:

Food and Drug Administration

Phone Number(s): (888) 463-6332

Internet Address: <http://www.fda.gov>

Cancer Information Service

Phone Number(s): (800) 422-6237

Internet Address: <http://cis.nci.nih.gov/>

National Library of Medicine

Phone Number(s): (888) 346-3656

Internet Address: <http://www.nlm.nih.gov/medlineplus/>

Osteoporosis and Related Bone Diseases National Resource Center

Phone Number(s): (800) 624-2663

Internet Address: <http://www.osteoporosis.org/>

National Osteoporosis Foundation

Phone Number(s): 1 (877) 868-4520

Internet Address: <http://www.nof.org/>

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This FAQ has been reviewed by Sherry Sherman, Ph.D., of the National Institute on Aging, National Institutes of Health.

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